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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,708	01/30/2001	Shankar Balasubramanian	106632	9485

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,708	BALASUBRAMANIAN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43,44 and 47-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43,44 and 47-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>0213</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

FINAL ACTION

1. This action is in response to papers filed 2 April 2003 in which claims 43-44 and 47-51 were amended, claims 45-46 were canceled and claims 52-54 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 9 September 2002 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(a); under 35 U.S.C. 102(b); and 35 U.S.C. 103(a) are maintained. All of the arguments have been thoroughly reviewed and are discussed below. New grounds for rejection necessitated by amendment are discussed.

Claims 43-44 and 47-54 are under prosecution.

Priority

2. The foreign priority claim filed on 4 June 2001 was not entered because the foreign priority claim was not filed during the time period set forth in 37 CFR 1.55(a)(1). For original applications filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, and any applications which applicant has requested voluntary publication, the time period is during the pendency of the application and **within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application**. For applications that have entered national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C.

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371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT. See 37 CFR 1.55(a)(1)(ii). If applicant desires priority under 35 U.S.C. 119(a)-(d), (f) or 365(a) based upon a prior foreign application, applicant must file a petition for an unintentionally delayed priority claim (37 CFR 1.55(c)). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.55(a)(1) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, D.C. 20231.

Applicant's claim for priority under 35 U.S.C. 119 as a CIP to PCT/GB99/02487 is acknowledged. However, the international application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 43-51 of this application. Claims 43-51 are drawn to a device comprising an array of polynucleotide molecules wherein each molecule comprises a polynucleotide duplex covalently linked to form a hairpin loop structure. The international application to which Applicant claims priority does not disclose the device comprising polynucleotide duplexes covalently linked to form a hairpin loop structure as instantly claimed. Therefore, the '02487 application does not provide support under 35 U.S.C. 112 for the instant claims.

the '02487 application does not provide support under 35 U.S.C. 112 for the instant claims, the effective filing date for the instant claims is the actual filing date of the instant application i.e. 30 January 2001.

Remarks

3. Applicant's petition is acknowledged. The petition will be processed subsequent to the mailing of this Office Action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 43, 44, 47, 50, 51, 53 and 54 are rejected under 35 U.S.C. 102(a) as being anticipated by Gunderson et al (EP 0 995 804 A2, published 26 April 2000).

Regarding Claim 43, Gunderson et al disclose a device comprising an array of polynucleotide molecules immobilized on a solid surface wherein each molecule comprises a polynucleotide duplex covalently linked to form a hairpin loop structure, one end of which comprises a target polynucleotide (i.e. probe) and the array has a surface density which allows the target polynucleotides to be individually resolved (page 9, ¶ 77-79; page 11, ¶ 100; and Fig. 1) and wherein adjacent molecules of the array are separated by a distance of at least 100µm i.e. each region upon which a distinct compound is synthesized is smaller than 1cm² and/or separated into wells (page 5, ¶ 40).

Regarding Claim 44, Gunderson et al disclose the device wherein immobilization to the solid surface is via covalent attachment (page 9, ¶ 77).

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Regarding Claim 47, Gunderson et al disclose the device wherein adjacent molecules of the array are separated by a distance of at least 250 μ m i.e. each region upon which a distinct compound is synthesized is smaller than 1cm² and/or separated into wells (page 5, ¶ 40).

Regarding Claim 50, Gunderson et al disclose the device wherein at least one polynucleotide molecule on the array has a second polynucleotide hybridized thereto (pages 10-11, ¶ 92-94).

Regarding Claim 51, Gunderson et al disclose the device wherein the polynucleotides are of known sequence i.e. complete n-mers (page 9, ¶ 78-79).

Regarding Claim 53, Gunderson et al disclose the structural limitations of the device of Claim 43. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114). Because the courts have stated that a device must be distinguished from the prior art in terms of structure and because Gunderson et al disclose the structural components of Claim 53, Gunderson et al disclose the claimed device.

Regarding Claim 54, Gunderson et al disclose the device wherein the polynucleotide duplex is covalently linked by a psoralen molecule to form a hairpin loop (Fig. 1 and ¶ 14).

6. Claims 43, 44, 47, 50, 51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockhart et al (WO 97/27317, published 13 July 1997).

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Regarding Claim 43, Lockhart et al disclose a device comprising an array of polynucleotide molecules immobilized on a solid surface wherein each molecule comprises a polynucleotide duplex covalently linked to form a hairpin loop structure, one end of which comprises a target polynucleotide and the array has a surface density which allows the target polynucleotides to be individually resolved (Abstract; page 6, second full paragraph; page 70, line 26-page 72, line 12; and Fig. 13 and 14) and wherein adjacent molecules of the array are separated by a distance of at least 10 μ m i.e. 60 different polynucleotides/cm² (page 7, second full paragraph).

Regarding Claim 44, Lockhart et al disclose the device wherein immobilization to the solid surface is via covalent attachment (page 29, second full paragraph, lines 20-22).

Regarding Claim 47, Lockhart et al disclose the device wherein adjacent molecules of the array are separated by a distance of at least 250 μ m i.e. 60 different polynucleotides/cm² (page 7, second full paragraph).

Regarding Claim 50, Lockhart et al disclose the device wherein at least one polynucleotide molecule on the array has a second polynucleotide hybridized thereto (Fig. 13-14).

Regarding Claim 51, Lockhart et al disclose the device wherein the polynucleotides are of known sequence (Abstract).

Regarding Claim 53, Lockhart et al disclose the structural limitations of the device of Claim 43. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114). Because the courts have stated that a device must be distinguished from the prior art in terms of structure and because Lockhart et al disclose the structural components of Claim 53, Lockhart et al disclose the claimed device.

7. Claims 43, 44, 47, 50, 51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Lane et al (WO 97/08183, published 6 March 1997).

Regarding Claim 43, Lane et al disclose a device comprising an array of polynucleotide molecules immobilized on a solid surface wherein each molecule comprises a polynucleotide duplex covalently linked to form a hairpin loop structure, one end of which comprises a target polynucleotide and the array has a surface density which allows the target polynucleotides to be individually resolved (page 8, first full paragraph, page 10, first full paragraph and Fig. 1) and wherein adjacent molecules of the array are separated by a distance of at least 250 μ m i.e. within separate wells of a 96-well plate (page 10, first full paragraph, lines 15-19).

Regarding Claim 44, Lane et al disclose the device wherein immobilization to the solid surface is via covalent attachment (page 9, first full paragraph, lines 10-15).

Regarding Claim 47, Lane et al disclose the device wherein adjacent molecules of the array are separated by a distance of at least 250 μ m i.e. within separate wells of a 96-well plate (page 10, first full paragraph, lines 15-19).

Regarding Claim 50, Lane et al disclose the device wherein at least one polynucleotide molecule on the array has a second polynucleotide hybridized thereto (Example 4, pages 18-19).

Regarding Claim 51, Lane et al disclose the device wherein the polynucleotides are of known sequence (i.e. complementary to a target sequence and Example 4, pages 18-19).

Regarding Claim 53, Lane et al disclose the structural limitations of the device of Claim 43. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120

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USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114). Because the courts have stated that a device must be distinguished from the prior art in terms of structure and because Lane et al disclose the structural components of Claim 53, Lane et al disclose the claimed device.

Response to Arguments

8. Applicant argues that none of the references cited above teach or suggest an array of molecules spaced at least 100nm apart. The argument has been considered but is not found persuasive because all of the cited references teach the array as claimed.

Applicant appears to be suggesting that the claims are drawn to separation between each single polynucleotide molecule. However, the claims are not drawn to separation between single molecules, but instead are drawn to separation between adjacent molecules. The claims are drawn to an array of nucleic acids “comprising” polynucleotide molecules and adjacent polynucleotide molecules immobilized on the array are separated by a distance of at least 100nm. Furthermore, the open claim language “comprising” encompasses additional components on the array. Therefore, any additionally array components (or molecules) taught by the cited references are encompassed by the instant claim language.

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 48-49 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane et al (WO 97/08183, published 6 March 1997) in view of Lockhart et al (WO 97/27317, published 13 July 1997).

Regarding Claim 48, 49 and 52, Lane et al teach a device comprising an array of polynucleotide molecules immobilized on a solid surface wherein each molecule comprises a polynucleotide duplex covalently linked to form a hairpin loop structure, one end of which comprises a target polynucleotide and the array has a surface density which allows the target polynucleotides to be individually resolved (page 8, first full paragraph, page 10, first full paragraph, page 15 and Fig. 1) wherein the molecules are immobilized to a surface e.g. membrane (page 10, first full paragraph, lines 15-19) but they do not specifically teach the density is 10^6 molecules per cm^2 (Claim 48); 10^7 to 10^8 molecules per cm^2 (Claim 49); or 10^9 molecules per cm^2 (Claim 52).

However, similar densities were well known in the art at the time the claimed invention was made as taught by Lockhart et al who teach a similar device having the similar densities comprising an array of polynucleotide molecules immobilized on a solid surface wherein each molecule comprises a polynucleotide duplex covalently linked to form a hairpin loop structure, one end of which comprises a target polynucleotide and the array has a surface density which allows the target polynucleotides to be individually resolved (Abstract; page 6, second full paragraph; page 70, line 26-page 72, line 12; page 30, second paragraph and Fig. 13 and 14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the high density teaching of Lockhart et al to the array of Lane et al to

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thereby provide for analysis of a large number of polynucleotides in a single analysis step for the obvious benefits of economy of time and labor. Additionally the courts have stated that a change in the size, shape and/or dimensions of a prior art device does not distinguish the device over the prior art.

In *re* Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. (see MPEP 2144.04 IV.A.)

11. Claims 48, 49 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunderson et al (EP 0 995 804 A2, published 26 April 2000).

Regarding Claim 48, 49 and 52, Gunderson et al teach the device having a density of from 10^6 to 10^9 molecules per cm^2 i.e. 10^4 to 10^6 per 0.25mm^2 (pages 9-10, ¶ 84) but they do not specifically teach the density is 10^6 molecules per cm^2 (Claim 48); 10^7 to 10^8 molecules per cm^2 (Claim 49); or 10^9 molecules per cm^2 (Claim 52);

However, the courts have stated where the claimed ranges "overlap or lie inside the ranges disclose by the prior art" and even when the claimed ranges and prior art ranges do not overlap but are closed enough that one skilled in the art would have expected them to have similar properties, a *prima facie* case of obviousness exists (see *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990);

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Titanium Metals Corp. of America v. Banner, 778 F.2d 775. 227 USPQ 773 (Fed. Cir. 1985) (see MPEP, 2144.05 I.). Therefore, the claimed ranges would have been obvious at the time the claimed invention was made because one of ordinary skill in the art would have expected the claimed ranged to have properties similar to those similar ranges disclosed by Gunderson et al.

12. Claims 48, 49 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al (WO 97/27317, published 13 July 1997).

Regarding Claims 48, 49 and 52, Lockhart et al teach the device having a density of from 10^6 to 10^9 molecules per cm^2 (page 30, second paragraph) but they do not specifically teach the density is 10^6 molecules per cm^2 (Claim 48); 10^7 to 10^8 molecules per cm^2 (Claim 49); or 10^9 molecules per cm^2 (Claim 52);

However, the courts have stated where the claimed ranges “overlap or lie inside the ranges disclose by the prior art” and even when the claimed ranges and prior art ranges do not overlap but are closed enough that one skilled in the art would have expected them to have similar properties, a *prima facie* case of obviousness exists (see *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775. 227 USPQ 773 (Fed. Cir. 1985) (see MPEP, 2144.05 I.). Therefore, the claimed ranges would have been obvious at the time the claimed invention was made because one of ordinary skill in the art would have expected the claimed ranged to have properties similar to those similar ranges disclosed by Lockhart et al

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
June 5, 2003